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James J. Sales
Eli Lilly and Company
Patent Division/jjs Lilly Corporate Center
Indianapolis IN 46285

Re: Patent Term Extension
Application for
U.S. Patent No. 4,418,068

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OFFICE OF PETITIONS

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,418,068, which claims the drug product EVISTA® (raloxifene hydrochloride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be two years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within two months of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are NOT applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of two years, which is the same period as the two previously granted interim extensions under 35 U.S.C. 156(e)(2).

The Food and Drug Administration (FDA) determination of the length of the regulatory review period was published in the Federal Register of 67 Fed. Reg. 9300 (February 2002). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= ½ (5,228 - 714) + 184
= 2,441 days

Since the regulatory review period began December 16, 1981, before the patent issue date (November 29, 1983), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From December 16, 1981 to and including November 29, 1983 is 714 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The two year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation, however, because the patent was issued and an action described in 35 U.S.C. § 156(g)(6)(B) was taken before the date of enactment of 35 U.S.C. § 156, September 24, 1984. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed two years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for **two years**.

On October 10, 2000, applicant filed a letter regarding the application for patent term extension, disclaiming the regulatory review related to the original IND filed on June 18, 1982, and all other regulatory activities prior to September 24, 1984, the effective date of 35 U.S.C. 156, and June 26, 1992, the date when a second IND was activated.

The determination of the regulatory review period by the regulatory agency is made based on the application as well as the official regulatory agency records for the approved product. See, e.g., 21 CFR Ch. 1, Subpart C. The determination of the length of the regulatory review period is solely the responsibility of the regulatory agency. Aktiebolaget Astra v. Lehman, 71 F.3d 1578,

1580-81, 37 USPQ2d 1212, 1214-15 (Fed. Cir. 1995); U.S. Patent No. 4,215,113. FDA has determined that the regulatory review period for the product EVISTA® (raloxifene hydrochloride) began on February 16, 1983. Accordingly, 35 U.S.C. § 156(g)(6)(C) limits the length of the patent term extension to two years. The USPTO has no authority to disregard part of the determination of the regulatory review period by FDA and to consider the period to have begun on a later date. As a result, applicant's disclaimers cannot be given legal effect.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,418,068
Granted:	November 29, 1983
Original expiration date:	April 3, 2001
Applicant:	Charles D. Jones
Owner of Record:	Eli Lilly and Company
Title:	Antiestrogenic and Antiandrogenic Benzothiophenes
Classification:	424/267
Product Trade Name:	EVISTA® (raloxifene hydrochloride)
Term Extended:	Two years
Expiration Date as extended:	April 3, 2003

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9411
Attn: Karin Ferriter

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Ferriter

Karin L. Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: David T. Read
Acting Director Health Assessment Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
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RE: EVISTA® (raloxifene hydrochloride)
FDA Docket No.: 99E-5114